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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/500,478

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Jan Sternby

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EXAMINER

KIM, SUN U

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/500,478	Applicant(s) STERNBY ET AL.	
	Examiner JOHN KIM	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 16-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-15 and 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/17/08</u> . | 6) <input type="checkbox"/> Other: _____ |

1. Claims 1-11 and 16-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was treated as an election **without** traverse in the reply filed on 10/29/07 as indicated in previous office action.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polaschegg et al (US Patent No. 4,702,829).

Regarding claim 27, Polaschegg et al teach a hemodiafiltration device comprising a blood circuit (104, 110, 106, 114), a fluid circuit (22, 24) and a filter (12) having a semipermeable membrane (14) separating a fluid compartment (16) from a blood compartment (12) provided with means (e.g. connection of 100 to 120) for mixing blood and a cleaning fluid and directing the mixture through the blood compartment (12) and means (66 e.g. ultrafiltrate pump) for applying a pressure gradient across the membrane (14) to create an ultrafiltration into the fluid compartment (16) wherein a water permeability coefficient of the filter (12) is at least 10 ml/min/mm Hg (see figure; col. 3, line 16 – col. 6, line 65; col. 9, lines 22-63). As noted in applicant's argument on page 12 of the response, the water permeability is converted to 15 ml/min/mmHg. Recitation of "configured to remove partially carrier bound substances from blood", "the cleaning fluid flow rate is at least 1000 ml/min and a ratio between the cleaning

fluid flow rate and a blood flow rate is at least 5" is an intended use of the apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Claim 27 essentially differs from the apparatus of Polaschegg et al in reciting creating ultrafiltration of mixture fluid into a fluid compartment equal in size to the sum of a flow rate of the cleaning fluid and a desired weight loss rate of the patient. Polaschegg et al teaches wide variety of water permeability coefficient of the semipermeable membrane employed (see col. 3, lines 33 – col. 4, line 2) for desired flow rate of fluid. It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the flow rate of cleaning fluid and a desired weight loss rate of patient, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In *re Aller*, 105 USPQ 233. Regarding claim 28, Polaschegg et al teach that the filter is replaced by several filters (44, 78) arranged in series or parallel or a combination thereof (see figure).

4. Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polaschegg et al as applied to claim 27 or 28 above, and further in view of Brugger et al (US Patent No. 6,572,641 B2). Regarding claims 29-30, Polaschegg et al do not suggest a heater for heating blood before it is returned to the patient. Brugger et al teach a blood warming device in connection to a device (60) including hemodiafiltration or ultrafiltration device to heat blood to protect against hypothermia in patients receiving blood and avoids the need for a separate drip chamber (see figure 3; col. 3, lines 20-29; col. 4, line 51 - col. 5, line 2). It would have been

obvious to a person of ordinary skill in the art to combine the hemofiltration device with blood warming device of Brugger et al along a path including returning blood to protect against hypothermia in patients receiving blood and avoids the need for a separate drip chamber as suggested by Brugger et al (see col. 3, lines 20-29).

5. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polaschegg et al in view of American Journal of Kidney Diseases, Vol. 38, No. 3 (September), 2001, pages 575-579 (hereinafter referred to as Leyboldt et al). Polaschegg et al teach a hemodiafiltration method comprising a blood circuit (104, 110, 106, 114), a fluid circuit (22, 24) and a filter (12) having a semipermeable membrane (14) separating a fluid compartment (16) from a blood compartment (12) provided with means (e.g. connection of 100 to 120) for mixing blood and a cleaning fluid and directing the mixture through the blood compartment (12) and means (66 e.g. ultrafiltrate pump) for applying a pressure gradient across the membrane (14) to create an ultrafiltration into the fluid compartment (16) wherein a water permeability coefficient of the filter (12) is at least 10 ml/min/mm Hg (see figure; col. 3, line 16 – col. 6, line 65; col. 9, lines 22-63). As noted in applicant's argument on page 12 of the response, the water permeability is converted to 15 ml/min/mmHg. Claim 12 essentially differs from the method of Polaschegg et al in reciting that creating ultrafiltration of mixture fluid into a fluid compartment equal in size to the sum of a flow rate of the cleaning fluid and a desired weight loss rate of the patient and the cleaning fluid flow rate is at least 1000 ml/min and a ratio between the cleaning fluid flow rate and a blood flow rate is at least 5. Polaschegg et al teaches wide variety of water permeability coefficient of the semipermeable membrane employed (see col. 3, lines 33 – col. 4, line 2) for desired flow rate of fluid. It would have been obvious to one having ordinary skill in the art at

the time the invention was made to optimize the flow rate of cleaning fluid and a desired weight loss rate of patient, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Leypoldt et al teach that the urea and creatinine mass transfer area coefficients were independent of blood flow rate but increased when dialysate i.e. cleaning fluid was increased from 500 to 800 ml/min in high flux dialyzers (see abstract in page 575). Hence, any dialysate flow rate greater than 1000 ml/min would further enhance mass transfer area coefficients of small solutes and the increased ratio between the dialysate flow rate and the blood flow rate would also enhance mass transfer area coefficients of small solutes for increased removal of small solutes through the membrane in high flux dialyzers. It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the dialysate flow rate as well as the ratio between the dialysate flow rate and the blood flow rate in the method of Polaschegg et al to arrive at optimal removal of small solutes by enhancing mass transfer coefficients of small solutes as suggested by Leypoldt et al, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 13, Polaschegg et al teach that the filter is replaced by several filters (44, 78) arranged in series or parallel or a combination thereof (see figure).

Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polaschegg et al in view of Leypoldt et al as applied to claim 12 or 13 above, and further in view of Brugger et al (US Patent No. 6,572,641 B2). Regarding claims 14-15, Polaschegg et al do not suggest heating

blood before being returned to the patient. Brugger et al teach that a blood warming device in connection to a device (60) including hemodiafiltration or ultrafiltration device to heat blood to protect against hypothermia in patients receiving blood and avoids the need for a separate drip chamber (see figure 3; col. 3, lines 20-29; col. 4, line 51 - col. 5, line 2). It would have been obvious to a person of ordinary skill in the art to heat returning blood to a patient in a final dialyzer to protect against hypothermia in patients receiving blood and avoids the need for a separate drip chamber as suggested by Brugger et al (see col. 3, lines 20-29).

6. Applicant's arguments with respect to claims 12-15 and 27-30 have been considered but are moot in view of the new ground(s) of rejection. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant's argument of lack of teaching of claimed water permeability coefficient in secondary references of Brugger or Leypoldt is deemed moot in view of the teaching of the claimed water permeability coefficient in Polaschegg et al reference.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN KIM whose telephone number is (571)272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John Kim/
Primary Examiner, Art Unit 1797

JK
8/4/08